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EDITORIAL COMMENT

A Step Forward in the Evaluation of Transcatheter Aortic Valve Implantation*

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The paper by Rodés-Cabau et al. (1) in this issue of the *Journal* is an important contribution in the evaluation of transcatheter aortic valve implantation (TAVI). It is the largest published series reporting in-hospital and midterm results of TAVI with the Edwards Sapien (Edwards Lifesciences, Inc., Irvine, California) prosthesis. Another strength of this report is to expand the feasibility and safety of TAVI outside a single expert center. TAVI was performed in 6 centers, thereby enabling a sufficient number of patients to be treated in each of them. The use of a standardized evaluation protocol was another important feature to ensure a homogenous use of TAVI targeting high-risk patients. In addition, the number of patients enables results to be assessed more accurately, predictive factors to be identified with an adequate statistical power, and subgroups of interest—such as patients with porcelain aorta or frailty—to be analyzed.

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The high rate of procedural success (93.3%) and the low procedural mortality (1.7%) have improved since the first pilot series (2) and are consistent with recent single-center series (3,4). The 30-day mortality was 10.4% and was mainly related to the evolutive stage of heart disease, as attested by the predictive value of pulmonary hypertension, severe mitral regurgitation, and the need for hemodynamic support. Severe hemodynamic impairment is also a risk factor for surgical aortic valve replacement, and this is an incentive to avoid the postponement of any intervention until severe hemodynamic impairment, which further increases the risk of all procedures (5). The predictive value of severe mitral regurgitation deserves additional studies, taking into account in particular the mechanism of regurgitation. Functional mitral regurgitation might be expected to improve after TAVI, because of the decrease in left ventricular systolic pressure and delayed reverse left ventricular remodeling. Conversely, there is a lower likelihood of observing an improvement in organic mitral regurgitation. The impact of mitral regurgitation on the choice between TAVI and surgery is an important issue, because adding a mitral procedure to surgical aortic valve replacement increases the operative risk, particularly in old patients who frequently have severe mitral annular calcification.

The 2-year survival rate of 64% is also consistent with previous single-center reports. Besides the weight of 30-day mortality, midterm mortality is strongly determined by noncardiac deaths, because 33% of late deaths were of respiratory origin. The small number of cardiac-related deaths can be interpreted as proof of sustained hemodynamic efficacy of TAVI, and this is obviously a major difference with balloon aortic valvuloplasty. However, the weight of late deaths of noncardiac origin also points out the need to improve the identification of patients whose life expectancy is more compromised by comorbidities than by heart disease itself. The weight of comorbidities in midterm mortality has also been demonstrated in surgical series, and therefore it is not surprising to observe their particular impact in a population characterized by a high frequency of comorbidities. In this study comprising approximately the same number of transfemoral and transapical procedures, the TAVI approach did not influence outcome. This issue is still debated and might be influenced by differences in the criteria for the choice of procedure and the multiplicity of confounding factors. Thus, the optimal TAVI approach remains an open question and is also likely to evolve with technical improvements increasing the number of candidates to the transfemoral route.

Another original aspect of the report by Rodés-Cabau et al. (1) is the specific study of patients with porcelain aorta or frailty. Porcelain aorta is a single condition that increases the risk of surgery due to technical impossibility and/or hazards related to clamping of ascending aorta. In this context, patient outcome is expected to be good, provided intervention on the aortic valve can be carried out without aortic clamping, as is the case with TAVI. The first confirmation of good midterm results after TAVI in patients with porcelain aorta is a relevant contribution of the present study. It seems also that patients with porcelain aorta can be treated with the transfemoral approach, although the transapical route was initially favored in this particular indication (6).

Frailty is a less well-defined but important condition to take into account when dealing with aortic stenosis in elderly patients. Frailty was frequent, accounting for as many as 25% of patients in this series. Besides comorbidities and frequently in combination with them, it is likely to play a role in denying any intervention in nearly one-half of high-risk patients with aortic stenosis (4). One of the important challenges concerning

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frailty is to assess its impact on life expectancy and quality of life, regardless of heart disease and comorbidities. Despite a lower Society of Thoracic Surgery score, frail patients had the same late survival after TAVI as other patients, thereby suggesting a negative prognostic impact of frailty. However, the current impact of frailty is difficult to assess, because of the lack of a clear and reproducible definition. The definition of frailty used in this article is subjective and cannot be reliably translated in other study populations. Future studies should aim at developing reliable indexes of frailty, and the expertise of geriatricians is likely to be helpful in this setting.

Growing evidence now confirms that TAVI is an effective and useful treatment for high-risk patients with aortic stenosis and that it can be implemented on a nationwide basis in a limited number of centers applying a careful screening and training process. Besides ongoing randomized trials, further large observational series of TAVI are needed to better assess the safety of the procedure and the durability of implanted valvular substitutes and to refine the identification of predictive factors of late results to improve patient selection. This is of particular importance, given the present and expected burden of aortic stenosis in elderly patients presenting with a high-risk profile. In this particularly heterogeneous population, much remains to be done to better identify the patients who will derive a real benefit from the procedure (i.e., those in whom the efficacy of TAVI will not be offset by the impact of comorbidities).

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REFERENCES

1. Rodés-Cabau J, Webb JG, Cheung A, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. J Am Coll Cardiol 2010;55:1080–90.
2. Eltchaninoff H, Zajarais A, Tron C, et al. Transcatheter aortic valve implantation: technical aspects, results and indications. Arch Cardiovasc Dis 2008;101:126–32.
3. Webb JG, Altwegg L, Boone R, et al. Transcatheter aortic valve implantation. Impact on clinical and valve-related outcomes. Circulation 2009;119:3009–16.
4. Himbert D, Descoutures F, Al-Attar N, et al. Results of transfemoral or transapical aortic valve implantation following a uniform assessment in high-risk patients with aortic stenosis. J Am Coll Cardiol 2009;54:303–11.
5. Iung B. Management of the elderly patient with aortic stenosis. Heart 2008;94:519–24.
6. Vahanian A, Alfieri O, Al-Attar N, et al. Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J 2008;29:1463–70.

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